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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,826	02/09/2004	Barry N. Gellman	MIY-P03-006	9242
28120	7590	02/12/2008		
ROPES & GRAY LLP PATENT DOCKETING 39/41 ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER LACYK, JOHN P	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 02/12/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/774,826

Applicant(s)

GELLMAN ET AL.

Examiner

John P. Lacyk

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 163-168, 170, 171, 173-180, 182-188, 190-198 and 200-206 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 163-168, 170, 171, 173-180, 182-188, 190-198 and 200-206 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/24/07; 11/08/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 175-180, 185-188 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5336231) in view of Norris et al, "Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach".

3. Adair teaches a system (as seen in Figures 28-37) capable of treating urinary incontinence comprising:

- a. a shaft (92) having a curved portion (93) and an interlocking mating structure (96) on a distal end of the shaft (92); and
- b. a sling assembly (90) having an end for receiving the distal end of the shaft (92), and a complementary interlocking mating structure (84);
- c. wherein the interlocking mating structure (96) of the shaft (92) is inserted into the complementary interlocking mating structure (84) of the sling assembly (90);
- d. wherein the mating structures (96, 84) are releasably lockable such that the shaft (92) is releasably lockable to the sling assembly (90);
- e. wherein the sling assembly (90) is indirectly connected to the shaft (92) and the complementary mating structure (84) is indirectly connected to the sling assembly (90); and

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wherein the sling assembly (90) comprises a sling (82). Adair teaches the claimed system except for the sling specifically being a flat shape. Norris et al teaches a sling for use in treating incontinence and teaches that it is well known to use a sling that has a flat shape (see Figure 2 and column 2 under "Technique"). A modification of Adair such that the suture used as a sling is substituted with a flat shaped sling as taught by Norris et al would have been obvious to one skilled in the art since the flat shaped sling would provide a little more surface area and allow for added support to treat incontinence. Therefore such a modification would have been obvious since this would be the mere substitution of one known type of sling to treat incontinence for another and would allow for added support and a more evenly distributed force on the body.

4. Claims 193-198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 4935027) in view of Norris et al.

5. Yoon teaches a system (as seen in Figures 1, 1E and 2A-10) capable of treating urinary incontinence comprising:

- a. a handle (20);
- b. a shaft (24a,b) attached to the handle (20) and having a channel (32) located at an end and a curved portion (as seen in Figure 1); and
- c. a sling assembly (30, 30a, 30i) having an end for associating with the channel (32) of the shaft (24a,b),

- d. wherein the channel (32) is releasable lockable for locking the end of the sling assembly (30, 30_o, 30_i) in the channel (32) (as described in lines 21-23, 57-58 of column 6, lines 1-19, 34-39, 60-68 of column 7 and lines 1-4 of column 8);
- e. wherein the system further comprises a spring loaded locking mechanism (44, 150) for locking the end of the sling assembly (30, 30_o, 30_i) in the channel (32);
- f. wherein the sling assembly (30, 30_o, 30_i) comprises an elongated extension located at the end of the sling assembly (30, 30_o, 30_i);
- g. wherein the sling assembly (30, 30_o, 30_i) comprises a sling (as described in lines 9-11 of column 2);

wherein in an alternate embodiment, the sling assembly (30, 30_o, 30_i) further comprises an aperture (as seen through 210) located at the end of the sling assembly (30, 30_o, 30_i) for advancing the sling assembly through the shaft (24b) (as seen in Figure 1E).

Yoon teaches the claimed system except for the use of a flat shaped sling. A modification of Yoon in view of Norris et al would have been obvious for the same reasons as discussed above with respect to Adair in view of Norris et al.

- 7. **Claims 182-184, 190-192 and 204-205** are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5336231) in view of Norris et al as applied to claims 175 and 185 above, and further in view of Wilkinson et al. (US 3580256).
- 8. Adair teaches a system capable of treating urinary incontinence comprising a shaft with a curbed portion and a sling assembly, wherein both the shaft and the sling

assembly have interlocking mating structures, as described above. However, the use of a pouch over any portion of the sling assembly is not taught.

9. Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

10. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Adair because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

11. **Claims 163-168, 170-171, 173-174 and 203** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 4935027) in view Norris et al and further in view of Wilkinson et al. (US 3580256).

12. Yoon teaches a system (as seen in Figures 1, 1E and 2A-10) capable of treating urinary incontinence comprising:

- a. a handle (20);
- b. a shaft (24a,b) attached to the handle (20) and having a channel (32) located at an end and a curved portion (as seen in Figure 1); and
- c. a sling assembly (30, 30a, 30i) having an end for associating with the channel (32) of the shaft (24a,b),

- d. wherein the channel (32) is releasable lockable for locking the end of the sling assembly (30, 30_o, 30_i) in the channel (32) (as described in lines 21-23, 57-58 of column 6, lines 1-19, 34-39, 60-68 of column 7 and lines 1-4 of column 8);
 - e. wherein the system further comprises a spring loaded locking mechanism (44, 150) for locking the end of the sling assembly (30, 30_o, 30_i) in the channel (32);
 - f. wherein the sling assembly (30, 30_o, 30_i) comprises an elongated extension located at the end of the sling assembly (30, 30_o, 30_i);
 - g. wherein the sling assembly (30, 30_o, 30_i) comprises a sling (as described in lines 9-11 of column 2);
 - h. wherein in an alternate embodiment, the sling assembly (30, 30_o, 30_i) further comprises an aperture (as seen through 210) located at the end of the sling assembly (30, 30_o, 30_i) for advancing the sling assembly through the shaft (24b) (as seen in Figure 1E).
14. While Yoon teaches that the sling assembly material comprises materials commonly used in the art, the use of a pouch over any portion of the sling assembly is not taught.
15. Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Yoon because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

13. **Claims 200-202 and 206** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 4935027) in view of Norris et al as applied to claim 193 above in view of Wilkinson et al. (US 3580256).

14. Yoon teaches a system capable of treating urinary incontinence comprising: a handle, a shaft having a channel and a curved portion, and a sling assembly, as described above. While Yoon teaches that the sling assembly material comprises materials commonly used in the art, the use of a pouch over any portion of the sling assembly is not taught.

17. Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Yoon because pouches or sleeves were

commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

6. Applicant's arguments with respect to claims 163, 175, 185 and 193 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P Lacyk/
Primary Examiner, Art Unit 3735

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Primary Examiner
Art Unit 3735

J.P. Lacyk